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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/522,010	11/09/2005	Lucie Germain	JG-SB-5208	5199

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EXAMINER	
LILLING, HERBERT J	
ART UNIT	**PAPER NUMBER**
1657	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/522,010	GERMAIN ET AL.	
	Examiner	Art Unit	
	HERBERT J. LILLING	1657	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 April 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-25* is/are pending in the application.

4a) Of the above claim(s) *20-25* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *20-25* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *18 January 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *09-23-2005*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

1. Receipt is acknowledged of an election response filed April 2, 2008.

2. Claims 1-25 remain pending in this application.

3. Applicant has elected with traverse Group I, claims 1-4 and 7-19.

Claims 20-25 have been withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected species or invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on April 2, 2008.

The restriction is proper in accordance with PCT practice as well as the search report submitted in the PCT which stated that there were:

"multiple (groups of) inventions in this international application as follows: “see page 5-6 of report.

This Examiner has stated in the first office action with respect to the restriction requirement: The inventions or groups of inventions are not so linked as to form a single general inventive concept under PCT Rule 13.1 is evidenced in view of the prior art of record drawn to US 5,955,110; US 5,885,619; US 6,176,880; US 5,922,028 and US 6,287,370.

The record clearly indicates that PCT Rule 13.1 was abided to in that the group of inventions **are not** “so linked as to form a single general inventive concept”.

Furthermore, it was also stated that:

Because these inventions are independent or distinct for the reasons given above and there would be a **serious burden on the examiner if restriction is not required** because the inventions require a different field of search due to divergent subject matter for a computerized search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

This Examiner has rejoined Invention II, claims 5-6, in view of art which was found during the search, **thus claims 1-19 have been examined**.

In addition, Applicant has traversed the species election. The species election as required by this Examiner was not a restriction requirement as drawn to separate inventions but an examination tool in accordance with Paragraphs 806.04 (a+).

This Examiner has been very lenient in view of the following which is available at any time to further limit the **number of species:**

> ***37 CFR 1.146. Election of species.***
>
> In the first action on an application containing a generic claim to a generic invention (genus) and claims to more than one patentably distinct species embraced thereby, the examiner may require the applicant in the reply to that action to elect a species of his or her invention to which his or her claim will be restricted if no claim to the genus is found to be allowable. However, **if such application contains claims directed to more than a reasonable number of species, the examiner may require restriction of the claims to not more than a reasonable number of species before taking further action in the application.**
>
> See MPEP § 806.04(d) for the definition

A reasonable number is highly subjective which may be three or even up to five. The number of species in this instant application is far above five.

Applicant is entitled to petition the above requirement.

4. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In *re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-19 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims of copending Application No. 10/495748 [**20050079604**] **or/and** 10/866708 [20050170501].

INSTANT CLAIMED INVENTION :

1. A method for preparing a human or animal tissue from at least one sheet of living tissue, the method comprising the steps of: (a) arranging said at least one sheet of living tissue to form a multi-layer stack of living tissue; and (b) applying a compressive force in a direction normal to the surface of the multi-layer stack of living tissue with a force-applying means at a pressure and for an amount of time sufficient to compress layers of tissue together for inducing adjacent layers of tissue to fuse or adhere to each other.

2. The method of claim 1, wherein said multi-layer stack is arranged on a substantially flat support.

3. The method of claim 1, **wherein said multi-layer stack of living tissue in step (a) is formed by superimposing two or more sheets of living tissue.**

4. The method of claim 1, wherein said multi-layer stack of living tissue is formed by folding a sheet of living tissue upon itself.

5. The method of claim 1, further comprising a step of anchoring s**aid multi-layer stack of living tissue with anchoring means before said step (**b) of applying a force, wherein said anchoring means applies sufficient tension across said multi-layer stack of living tissue to prevent shrinkage and/or maintain cellular differentiation and/or induce fiber orientation.

6. The method of claim 5, wherein said anchoring means comprises a multiplicity of spaced apart weights or ingots arranged substantially around the perimeter of said multi-layer stack of living tissue.

7. The method of claim 1, wherein said force-applying means in step (b) comprises a weighted device suitable for applying substantially evenly-distributed pressure to said multi-layer stack of living tissue, said weighted device being at least partially permeable to tissue-culture medium. .

8. The method of claim 1, wherein the multi-layered stack of living tissue in step (a) is formed by **rolling a sheet of living tissue on a tubular support.**

9. The method of claim 8, wherein said force-applying means in step (b) comprises a tissue-culture medium permeable elastic sleeve.

10. (Currently amended) The method of claim 1, wherein cells are obtained from said at least one sheet of living tissue, said at least one sheet of living tissue is obtained via is a biopsy.

11. (Original) The method of claim 1, wherein said at least one sheet of living tissue is obtained by culturing cells in vitro.

12. (Original) The method of claim 11, wherein said cells are selected from the group consisting of embryonic stem cells, post-natal stem cells, adult stem cells, mesenchymal cells, hepatocytes, islet cells, parenchymal cells, osteoblasts and other cells forming bone or cartilage, and nerve cells.

13. (Original) The method of claim 12, wherein said mesenchymal cells are selected from the group consisting of fibroblasts, interstitial cells, endothelial cells, smooth muscle cells, skeletal muscle cells, myocytes, chrondocytes, adipocytes, fibromyoblasts, and ectodermal cells.

14. (Original) The method of claim 1, wherein said at least one sheet of living tissue is selected from the group consisting of a skin tissue, a corneal tissue, a cardiac valve tissue, a connective tissue and a mesenchymal tissue.

15. (Original) A multi-layer tissue made according to the method of claim 1, wherein said multi-layer tissue comprises at least two different types of sheets of living tissue.

16. (Original) A multi-layer tissue according to claim 15, consisting essentially of between two sheets and twelve sheets of living tissue.
17. (Original) A multi-layer tissue according to claim 15, consisting essentially of between three sheets and nine sheets of living tissue.
18. (Original) A multi-layer tissue according to claim 15, wherein said tissue has a thickness of about 0.01 mm to about 0.5 mm.
19. (Original) A multi-layer tissue according to claim 18, wherein said tissue has a thickness of about 0.03 ~~mm~~ to about 0.45 mm.

Although the conflicting claims are not identical, they are not patentably distinct from each other because they do not have the exact wording.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

I. The current claims for 10/495748 [20050079604] are considered to be clearly within the scope of the instant claims.

1. A method for increasing the functionality of a human or an animal tissue by applying at least one mechanical strain in at least one orientation to said tissue or components of said tissue for a period of time sufficient for causing the organization of cells and extracellular matrix components contained in said tissue or in components of said tissue.

2. The method of claim 1, wherein said tissue comprises at least one sheet of living tissue to form living tissue sheets.

3. The method of claim 2, wherein said living tissue sheets are assembled into tissue constructs.

4. A method of claim 1 comprising culturing said tissue in a medium containing a cell proliferation inhibitor or a cell cycle inhibitor for a period of time sufficient for inducing differentiation of cells contained in said tissue.

5. The method of claim 4, wherein said cells when differentiated are cultures for a period of time sufficient for the assembly of said cells into a tissue construct.

6. The method of claim 1, wherein said functionality is at least one of the following: mechanical resistance, contractility, transparency or responsiveness of the cells to biologically active compounds.

7. A method of claim 1, wherein said functionality could be improved by the cyclic traction, the pulsatile pressure, or a combination thereof.

8. The method of claim 1, wherein said tissue is a biopsy.

9. The method of claim 1, wherein said tissue is a tissue construct obtained by in vitro culture of cells assembled in a self-produced matrix.

10. The method of claim 1, wherein said tissue is a tissue construct obtained by in vitro culture of cells seeded onto a scaffold.

11. The method of claim 1, wherein said tissue is tubular or planar.

12. The method of claim 1, wherein said tissue is a vascular tissue, a skin tissue, a corneal tissue, a valve tissue, a connective tissue or a mesenchymal tissue.

13. The method of claim 1, wherein said organization is a parallel, transversal, or linear alignment of said cells, or a combination thereof

14. The method of claim 1, wherein said cells are mesenchymal cells or mesodermic cells.

II. **10/866708** 20050170501

According to another embodiment of the present invention, it will be understood that the tissue sheets can be made of several superimposed layers of sheets. This can be defined as being a tri-dimensional tissue construct. Among the tissue substitutes that can be considered, but without limitation, are collagen gels cast with living cells, a cellular matrices or synthetic materials. Alternatively, when performing the method of the present invention the tissue sheets can be replaced by biopsies or other tissue substitutes before fusing them into a continuous tissue construct. It will be recognized by someone skilled in the art that the latter, obtained under different configurations or forms, can constitute or be used as a graft or a replacement tissue.

III. 11/603865 [20070111307]

The rolling the continuous paper is within the scope of the claimed invention which contains a folded sheet which also contains

16. A method for producing a tubular tissue construct comprising rolling the continuous tissue construct of claim 1.

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Murphy et al 20020172705; **Murphy; Michael P., et al.** 20080108134; Binette**, Francois, et al 20040078090;** WO/00/29553.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Murphy et al 20020172705. 13 Mar 00. 21 Nov 02. " Bioengineered tissue constructs and methods for producing and using thereof"

Teaches the following which contains two layers that is considered to render the instant claims prima facie obvious to have one sheet layered over a second sheet and the weight of the first sheet would be normally capable of pressing over the under layer to adhere to each other over time.

16. A cultured skin construct having at least two layers, comprising: (a) a first layer of cultured dermal fibroblasts cells cultured under conditions to produce a layer of extracellular matrix which is synthesized and assembled by the cultured fibroblast cells, with the cultured fibroblast cells contained within the synthesized extracellular matrix layer, wherein the extracellular matrix comprises: (i) type I and type III collagen showing a packing organization of fibrils and fibril bundles exhibiting a quarter-staggered 67 nm banding pattern; (ii) decorin; (iii) fibronectin, (iv) tenascin; and, (v) glycosaminoglycans; wherein said extracellular matrix is produced by the cultured dermal fibroblast cells in the absence of exogenous matrix components or synthetic members during the culturing conditions; and, (b) a second layer of keratinocyte cells disposed on the first layer to form an epidermal cell layer, wherein the epidermal cell layer is a multilayered, stratified, differentiated and exhibits a basal layer, suprabasal layer, a granular layer and a stratum corneum; and wherein the bilayered cultured skin construct has a basement membrane present at the junction of the first and second layers.

Murphy; Michael P., et al. 20080108134. 31 Oct 07. 08 May 08.

Bioengineered Tissue Constructs and Methods for Producing and Using Thereof.

[Abstract] The disclosure of which renders the instant claims prima facie obvious for the basic issue of having at least one sheet of living tissue which can be used in a folded manner or combinations that forms a layered tissues which tissues are within the claimed living Cultured tissue constructs comprising cultured cells and endogenously produced extracellular matrix components without the requirement of exogenous matrix components or network support or scaffold members. Some tissue constructs of the invention are comprised of multiple cell layers or more than one cell type. The tissue constructs of the invention have morphological features and functions similar to tissues their cells are derived and their strength makes them easily handleable. Preferred cultured tissue constructs of the invention are prepared in defined media, that is, without the addition of chemically undefined componentstissues and cells thereof.

[0005] The invention is also directed to methods for producing tissue constructs by stimulation of cells in culture, such as fibroblasts, to produce extracellular matrix components in a defined medium system and/or without the use of undefined or non-human-derived biological components, such as bovine serum or organ extracts.

[0006] Further, this tissue construct can be made by serial seedings of different cell types to produce a cultured tissue construct that mimics the cell composition and tissue structures of native tissues.

A method for producing a bilayered cultured tissue construct, comprising: (a) seeding fibroblast cells capable of synthesizing an extracellular matrix on a porous membrane in a culture vessel in a first cell culture medium; (b) culturing the fibroblast cells of step (a) in the first cell culture medium to between about 80% to about 100% confluence on the porous membrane; (c) stimulating the fibroblast cells of step (a) to synthesize, secrete and organize extracellular matrix components under culturing conditions in a second culture medium; (d) continued culturing of the fibroblast cells until the cells form a layer of synthesized extracellular matrix of at least 30 microns thick, with the cultured fibroblast cells surrounded by the synthesized extracellular matrix layer, wherein said extracellular matrix is produced by the cultured fibroblast cells in the absence of exogenous matrix components or synthetic members during the culturing conditions; (e) seeding epithelial cells to the top surface the synthesized extracellular matrix of step (d), and, (f) stimulating the epithelial cells of step (e) under culturing conditions to form a bilayered tissue construct of an extracellular matrix, with the cultured fibroblast cells surrounded by the synthesized extracellular matrix layer, and a second layer of epithelial cells

Binette, Francois, et al 20040078090. 25 Feb 03. 22 Apr 04. "Biocompatible scaffolds with tissue fragments"

[0116] The tissue repair implant can be utilized in a variety of configurations. For example, the implant can be folded or stacked in multiple laminates or it can be rolled into the shape or a tube-like structure.

[0106] The composition, thickness, and porosity of the fibrous layer may be controlled to provide the desired mechanical and biological characteristics. For example, the bioabsorption rate of the fibrous layer may be selected to provide a longer or shorter bioabsorption profile as compared to the underlying biocompatible scaffold. Additionally, the fibrous layer may provide greater structural integrity to the composite so that mechanical force may be applied to the fibrous side of the structure. In one embodiment the fibrous layer could allow the use of sutures, staples or various fixation devices to hold the composite in place. Generally, the fibrous layer has a thickness in the range of about 1 micron to 1000 microns. However, for some applications such as rotator cuff and meniscus injury repair, the fibrous layer has a thickness greater than about 1.5 mm.

The invention also relates to methods of treating tissue using the biocompatible tissue implants of the present invention. Tissue treatment according to these methods can be performed by providing a biocompatible scaffold and a sample of minced tissue, depositing the tissue sample upon the biocompatible scaffold, and placing the tissue-laden scaffold in a desired position relative to the tissue to be treated. In one embodiment, tissue repair can be achieved by providing a biocompatible scaffold and a sample of minced tissue, depositing the tissue sample in a desired position relative to the tissue injury, and placing the biocompatible scaffold over the tissue. In another embodiment, the method of producing these implants can include the further step of incubating the tissue-laden scaffold in a suitable environment for a duration and under conditions that are effective to allow cells within the tissue sample to populate the scaffold. In yet another embodiment, the methods of treating tissue can also include the additional step of affixing the scaffold in a desired position relative to the tissue to be treated, such as, for example, by fastening the tissue-laden scaffold in place.

[0016] The present invention is also directed to methods for measuring the effect(s) of a substance on living tissue. According to this aspect of the invention, the bioimplantable tissue implants of the present invention can be used to create tissue constructs that can be contacted with a test substance so that the effects of the substance on living tissue can be observed and measured. Thus, the bioimplantable tissue constructs of the present invention can be used as a biological screening assay to measure the effects of a test substance on living tissue by examining the effect on various biological responses, such as for example, the effect on cell migration, cell proliferation and differentiation and maintenance of cell phenotype.

[0017] In embodiments in which the implant is used for tissue repair, the tissue repair implant can be used to treat a variety of injuries, such as for example, injuries occurring within the musculoskeletal system, such as rotator cuff injuries, ACL ruptures, or meniscal tears, as well as injuries occurring in other connective tissues, such as skin and cartilage. Furthermore, such implants can be used in other orthopaedic surgical procedures, such as hand and foot surgery, to repair tissues such as ligaments, nerves, and tendons.

[0019] FIG. 1A is photomicrograph that demonstrates that cells in a cartilage tissue sample migrate extensively into a polymer scaffold;

[0021] FIG. 2A is a photomicrograph that demonstrates that cells within the minced tissue loaded on the biocompatible scaffolds, following implantation into SCID mice, have proliferated and filled the entire scaffold;

Furthermore for **claim 11** the formation of a sheet of living tissue:

A method for measuring the effect of a substance on living tissue, comprising the steps of: (a) creating a tissue construct by providing a biocompatible scaffold, obtaining a sample of tissue, processing the sample of tissue to form at least one tissue fragment, depositing the at least one tissue fragment on the biocompatible scaffold such that the at least one tissue fragment is associated with the biocompatible scaffold, thereby forming a tissue construct, and incubating the tissue construct for a duration and under conditions that are effective to allow cells within the tissue fragment to populate the scaffold; (b) contacting the tissue construct with a substance; and (c) determining the effects of the substance on the tissue construct.

In view of the following disclosure, claims 5 and 6 have been rejoined:

The method of claim 79, wherein the effective amount of cells migrate out of the tissue fragment and populate at least a portion of an interior region of the scaffold, such that the cells are embedded within the scaffold.

82. The method of claim 71, further comprising the additional step of providing at least one additional bioimplantable scaffold and placing the at least one additional bioimplantable scaffold over the deposited at least one tissue fragment, such that at least a portion of the at least one tissue fragment is disposed between at least two bioimplantable scaffolds.

83. The method of claim 71, wherein the bioimplantable scaffold further comprises an adhesion agent for anchoring the at least one minced tissue fragment to the bioimplantable scaffold.

91. The method of claim 71, wherein the bioimplantable scaffold comprises a polymeric foam component having pores with an open cell pore structure

The disclosure renders claims 5 and 6 prima facie obvious to anchor the sheets around the perimeter to maintain the living tissues in a secure embedded place within the scaffold.

For claims 12-14, the disclosure which tissues would have the cells associated with the following tissues:

76. The method of claim 71, wherein the at least one tissue fragment comprises tissue selected from the group consisting of cartilage tissue, meniscal tissue, ligament tissue, tendon tissue, skin tissue, muscle tissue, periosteal tissue, pericardial tissue, synovial tissue, nerve tissue, kidney tissue, bone marrow, liver tissue, bladder tissue, pancreas tissue, spleen tissue, and combinations thereof.

Thus, the above references consider the claimed inventions unpatentable over the references alone or further in view of each other based on actual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966) since the references discloses the basic issues for one of ordinary skilled in the art absence unexpected process steps which this Examiner cannot find in the instant specification pertaining to the sheets, stacking, force applying, time for compressing to adhere, anchoring, folding, biopsy, culturing, cells or thickness which references clearly render the specific process steps obvious.

Even if there is a difference, this Examiner considers that further in light of the Supreme Court's recent decision in KSR International Co. v. Teleflex Inc (TFX) ., 82 USPQ2d 1385 (2007) based on the reasoning may still include the established Court of Appeals for the Federal Circuit standard that a claimed invention may be obvious if the examiner identifies a prior art teaching, suggestion, or motivation (TSM) to make it, however, the Guidelines explain that **there is no requirement that patent examiners use the TSM approach in order to make a proper obviousness rejection.** Furthermore, the Guidelines point out that even if the TSM approach cannot be applied to a claimed invention, that invention may still be found obvious. This Examiner will consider any reasonable showings in the specification or declaration submitted on the next response prior to any Final Rejection.

6. **No claim is allowed.**

7. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Lilling whose telephone number is 571-272-0918 and Fax Number is **571-273-8300**. or SPE Jon Weber whose telephone number is 571-272-0925. Examiner can be reached Monday-Friday from about 7:30 A.M. to about 7:00 P.M. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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Art Unit **1657**
May 13, 2008

/HERBERT J LILLING/
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